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(21) International Application Number: PCT/EP98/02613 (22) International Filing Date: 4 May 1998 (04.05.98) (30) Priority Data: MI97A001091 9 May 1997 (09.05.97) IT (71) Applicant (for all designated States except US): VANDER WAY LIMITED [IE/IE]; 17 Dame Street, Dublin 2 (IE). (72) Inventor; and (75) Inventor/Applicant (for US only): BARTORELLI, Luisa [IT/IT]; Via Fogazzaro, 20, I-20135 Milano (IT). (74) Agent: MINOJA, Fabrizio; Bianchetti Bracco Minoja S.r.l., Via Rossini, 8, I-20122 Milano (IT).	(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>	
(54) Title: PHARMACEUTICAL FORMULATIONS CONTAINING COLOSTRUM AND THE USE OF COLOSTRUM FOR THE TREATMENT OF AFFECTIONS OF THE ORAL CAVITY (57) Abstract Pharmaceutical formulations containing animal colostrum for the treatment of affections of the oral cavity.		

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PHARMACEUTICAL FORMULATIONS CONTAINING COLOSTRUM AND THE
USE OF COLOSTRUM FOR THE TREATMENT OF AFFECTIONS OF THE
ORAL CAVITY

The present invention relates to pharmaceutical formulations containing animal colostrum for the treatment of affections of the oral cavity, and the use of colostrum for the treatment of said affections.

5 "Affections of the oral cavity" means, in particular, stomatitis, prosthetic stomatitis, gingivitis, periodontal diseases, pyorrhea alveolaris; mucositis, chemotherapy and radiotherapy sores and ulcers; inflammations and ulcerations of the oral
10 mucosa.

Poor oral hygiene, infections, local mechanical traumas, immune deficiencies, autoimmune disorders, avitaminosis, infective, toxic or irritating agents, systemic diseases, allergic sensitizations can be cited
15 among the known agents responsible for the above mentioned oral affections.

Therapy mainly depends on the etiologic agent: treatment usually consists, in addition to a better oral hygiene, in the administration of disinfectants,
20 astringents, antibacterials, such as chlorhexidine and quaternary ammonium salts; antibiotics, such as penicillin and tetracyclines; antimycotics, such as ketoconazole; steroids, such as dexamethasone, prednisolone and triamcinolone acetonide; local
25 anaesthetics, such as benzocaine and lidocaine; as well as the elimination of any mechanical factors such as malocclusion, substitution of prosthesis, and the like.

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The use of medicaments such as antibiotics, antimycotics and steroids can, of course, involve untoward side-effects, or it can be limited or precluded by the conditions of the patient. An agent which, although exerting remarkable antiinflammatory and antibacterial actions on the above cited conditions, involve no undesired side-effects is therefore strongly needed.

The present invention aims at overcoming the above mentioned problems by using topical pharmaceutical formulations containing equine, bovine or anyway mammal, but preferably equine, colostrum, for the treatment of affections of the oral cavity.

The present invention further relates to the use of equine, bovine or anyway mammal, but preferably equine, colostrum, as an agent for the treatment of the affections of the oral cavity.

Now it has surprisingly been found that colostrum, when administered to patients suffering from affections of the oral cavity, acts favourably exerting an antiinflammatory effect and restoring the physiological conditions of the buccal mucosa in a short time.

The pharmaceutical formulations of the invention comprise topical formulations containing powder or liquid colostrum in amounts up to 30% by volume of the formulation. The powder colostrum can be in the freeze-dried or sprayzed form.

More particularly, the formulations of the invention comprise collutories, liquid or in sachets to dilute before use, for the administration to the oral cavity by means of gurgles and washings with undiluted

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solutions, spray for nebulizations, gingival gels for gingival massages, tooth-pastes or tablets to dissolve slowly in the mouth.

5 The compositions of the invention are prepared according to the conventional pharmaceutical techniques for the preparation of topical formulations for the treatment of the oral cavity.

10 The formulations of the invention will be used by the patient 1 to 3 times a day, particularly in the morning and at night after brushing teeth.

According to a further aspect of the invention, the formulations can contain colostrum mixed with antibacterial agents, such as chlorhexidine and benzidamine, antiinflammatory agents, local anaesthetics
15 such as lidocaine and benzocaine, vegetable extracts having astringent or antiinflammatory action, essential oils of sage, fennel, peppermint and clove, and the like.

20 The formulations will also contain the conventional excipients used for the preparation of oral topical formulations.

The following examples illustrate formulations according to the present invention.

EXAMPLE 1

25 20% Colostrum gingival gel

200 ml of gel contain (in % by volume):

colostrum	20
propylene glycol	1
chlorhexidine digluconate	0.5
30 methyl p-hydroxybenzoate	0.7
propyl p-hydroxybenzoate	0.7

essential oils and flavours⁴ 1.2%
micronized silica 10%
water q.s. to 200 ml

EXAMPLE 2

5 30% Colostrum collutory
100 ml of collutory contain (in % by volume):
colostrum 30
ethyl p-hydroxybenzoate 0.7
benzidamine 0.5
10 benzocaine 2.5
natural flavours 2
distilled water q.s. to 100 ml

EXAMPLE 3

20% Colostrum gingival gel
15 200 ml of gel contain (in % by volume):
colostrum 20
micronized silica 10
fennel essential oil 1.5
sage essential oil 2.0
20 methyl p-hydroxybenzoate 1.5
propyl p-hydroxybenzoate 1.5
chlorhexidine digluconate 0.5
natural flavours 1.5
distilled water q.s. to 200 ml.

CLAIMS

1. Topical pharmaceutical formulations containing colostrum for the treatment of affections of the oral cavity.
2. Pharmaceutical formulations according to claim 1, in which colostrum is equine, bovine or anyway mammal, but preferably equine, colostrum.
3. Formulations according to claims 1 and 2, in the form of collutory or tooth-paste containing powder or liquid colostrum.
4. Formulations according to the above claims, in which the powder colostrum is freeze-dried or sprayzed.
5. Formulations according to the above claims, further containing powder milk.
6. The use of colostrum for the preparation of a medicament for the treatment of affections of the oral cavity.

INTERNATIONAL SEARCH REPORT

national Application No

PCT/EP 98/02613

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61K35/20 A61K7/26 A61K9/08 //A61K9/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 743 060 A (SARA LEE/DE N.V.) 20 November 1996	1-4,6
Y	see the whole document ---	5
X	WO 94 16675 A (HORSE VITALITY LTD.) 4 August 1994	1-5
Y	see claims -----	5

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☒ Patent family members are listed in annex.

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Information on patent family members

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